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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,124	07/18/2003	Martin F. Bachmann	1700.0340001/BJD/SJE	3313

26111 7590 07/25/2007

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,124	BACHMANN ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 19, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19,21-34,55,61-63 and 68-96* is/are pending in the application.

4a) Of the above claim(s) *5, 9, 10, 61, 62, 74, 90 and 96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,11-15,19,21-34,55,63,68-73,75-89 and 91-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 18, 2006 in response to the Office Action of July 20, 2006 and the Supplemental reply filed April 19, 2007 in response to the Office communication of January 26, 2007 are acknowledged and entered. Claims 16-18, 20, 35-54, 56-60 and 64-67 have been canceled. Contrary to the Applicant's assertion Examiner did not withdraw claim 12 for being directed to non-elected species. SEQ ID NO: 4 recited in claim 12 was elected by the Applicant in response of May 4, 2006 (see Remarks page 23). Claim 12 was examined in the Office action of July 20, 2006. Thus claim 12 is currently under examination. Claim 30 was examined on the merits in the Office action of July 20, 2006, because claim 30 recites elected species of SEQ ID NO: 65. Examiner inadvertently indicated claim 30 as being withdrawn on the Office Action Summary of July 20, 2006. Claim 30 is under examination. Claims 1, 25, 30, 55, 63, 70, 71, and 77 are amended. New claims 91-96 are added. Pending claims 5, 9, 10, 61, 62, 74, 90 and new claim 96 are withdrawn from consideration. New claim 96 is withdrawn because it is drawn to non-elected invention. Claims 1-4, 6-8, 11-15, 19, 21-34, 55, 63, 68-73, 75-89, and 91-95 are under examination in the present Office action.

Election/Restriction

Applicant's arguments in response to the notice of Non-responsive amendment have been considered. Applicant amended the independent claim 1 to recite SEQ ID NO: 119 representing the ghrelin peptide. Applicant argues that the ghrelin peptide of SEQ ID NO: 119 is a common structural feature present in the elected SEQ ID NO: 31 and 65, as well as in the remaining sequences recited in the pending claims. Applicant canceled the sequences that do not comprise

SEQ ID NO: 119. Upon further consideration SEQ ID NO: 119 is rejoined because it represents the sequence of the ghrelin peptide that was recited in claim 1 prior Applicants amendment.

Applicant states that Examiner did not acknowledge all elected species, particularly SEQ ID NO: 31. Examiner notes that SQ ID NO: 31 together with SEQ ID NO: 65 and SEQ ID NO: 4 were examined on the merits in the Office action of July 20, 2006. Examiner acknowledges that the elected species are Q-beta phage, SEQ ID NO: 4, SEQ ID NO: 31, SEQ ID NO: 65 and the currently rejoined SEQ IDNO: 119. It is noted that the remaining sequences comprising SEQ ID NO: 119 that are recited in the claims are not rejoined and are not examined.

Claim Objections

Objection to claims 61, 64, 68, 69, 70, 71, 72, 76, 77, 78, 79, 80, 82, 83, 84, and 85 under 37 CFR 1.75 as being a substantial duplicates of claims 1, 4, 6, 7, 8, 9-11, 12, 15, 19, 22, 23, 25, 27, 28, 29, 30, and 31 is withdrawn in view of Applicants amendment and arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of Claims 1-3, 15, 19, 21-31, 32-34, 55, 63, 64, and 76-85 **and new claims 91-95** under 35 U.S.C. 103(a) as being unpatentable over Sebbel et al., (US Patent 6,964,769 B2, herein, "Sebbel") in view of Kojima et al (Nature, 1999, herein, "Kojima") **is maintained.**

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that there is no reason, suggestion, or motivation in Sebbel or Kojima that would lead one of ordinary skill in the art to combine the references, and that Examiner has not met the burden of establishing a *prima facie* case of obviousness based on Sebbel in view of Kojima. Applicant amended the claims to recite SEQ ID NO: 119 representing the ghrelin peptide. Applicant argues that neither Sebbel nor Kojima disclose, suggest or motivate to use ghrelin peptides as antigens wherein said ghrelin peptide comprises SEQ ID NO: 119, as antigenic determinants to form an ordered and repetitive antigen array as required by present independent claim 1. Applicant argues that Kojima does not disclose or suggest the skilled person in the art to use ordered and repetitive antigen arrays comprising ghrelin peptides associated with core particles as prophylactic or therapeutic means for the treatment of obesity. Examiner respectfully disagrees with Applicant's position. It is noted that the present claims are not drawn to the methods for treatment of obesity, nor do the claims recite the intended use of the presently claimed composition. Even if the claims drawn to the composition recited the intended use, such as treatment of obesity, the intended use would not be limiting. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed.Cir. 1997). Thus the fact that Sebbel or Kojima do not suggest using repetitive antigen arrays comprising ghrelin peptides associated with core particles, as prophylactic or therapeutic means for the treatment of obesity is irrelevant.

It is noted that the ghrelin peptide taught by Kojima comprises the currently claimed SEQ ID NO: 119 (see Figure 4). Thus Kojima teaches the limitation of SEQ ID NO: 119. With respect to Applicant's argument about the absence of a teaching in Sebbel and Kojima about antigenic

determinants forming an ordered and repetitive antigen array, it is noted that Sebbel teaches VLPs and Q-beta phage conjugated antigens, which form repetitive antigen arrays (see column 5, lines 23-31). Thus the composition comprising a VLP and/or Q-beta phage conjugated to an antigen of interest will result in the antigenic peptide organized in a repetitive antigen array. It is understood that the repetitive antigen array results due to properties of VLPs and bacteriophages to which the antigens of interest are coupled. Sebbel teaches that any virus known in the art having an ordered and repetitive coat and/or coat protein structure may be selected as a non-natural molecular scaffold (see column 16, lines 58-68). The present specification teaches:

[0019] "(...), the highly repetitive and organized structure of the core particles and VLPs, respectively, mediates the display of the ghrelin or ghrelin-derived peptide in a highly ordered and repetitive fashion leading to a highly organized and repetitive antigen array."

[0190] "(...) the use of the VLPs as carriers allow the formation of robust antigen arrays and conjugates, respectively, with variable antigen density. In particular, the use of VLPs of RNA phages, and hereby in particular the use of the VLP of RNA phage Q.beta. coat protein allows achievement of a very high epitope density."

Therefore the cited references, in combination, teach the claim limitations such as the repetitive antigen array comprised of a Qß bacteriophage and a ghrelin peptide.

With regard to Applicant's argument about the absence of motivation to combine the references, it is noted that Sebbel teaches that any antigen of choice could be coupled to the surface of a VLP or a bacteriophage for the purposes of efficient induction of specific immune responses (see column 6, lines 21-38). Because the ghrelin peptide is regarded as an antigen and the immunization with an antigenic peptide typically results in generation of immune responses,

and because Sebbel teaches that coupling peptides of interest to VLPs or bacteriophages would result in generation of immune responses, the skilled person in the art would have been motivated to provide a composition comprising a VLP or Q-beta phage coupled to ghrelin peptide taught by Kojima.

Applicant argues that Sebbel does not disclose or suggest using ghrelin peptides as antigens to form an ordered and repetitive antigen array with VLPs of an RNA-bacteriophage by way of non-peptide bond as required by present amended independent claim 63. Examiner respectfully disagrees. Sebbel teaches a VLP bacteriophage coupled to an antigen by way of non-peptide bond (see column 5, lines 21-38, and column 10, lines 28-33, column 16, lines 58-68). Sebbel teaches that any virus known in the art having an ordered and repetitive coat and/or coat protein structure may be selected as a non-natural molecular scaffold. Sebbel dose not specifically teach an RNA bacteriophge. However the skilled person in the art would have been motivated to use an RNA bacteriophage as long as the RNA bacteriophage provides an ordered and repetitive coat. Thus because Sebbel teaches the claim limitation such an ordered and repetitive antigen array with VLP bacteriophage by way of non-peptide bond, it would have been obvious to the skilled person in the art to provide the composition of the present invention. It is noted that due to the amendment, claim 63 is now also rejected under the second 103(a) rejection following below.

With regard to new claims 91-95, Sebbel teaches the claim limitations as follows: Sebbel teaches association of second attachment site with the first attachment site through non-peptide covalent bond (see column 10, lines 28-33). Sebbel teaches second attachment site comprising a sulfhydryl group (see column 16, lines 39-57). Sebbel teaches that the first attachment site is a

lysine residue and the second attachment site is a cysteine residue (see column 20, lines 31-48). Kojima et al. teach a human ghrelin peptide, which has the sequence identical to the sequence of the instantly claimed SEQ ID NO: 31 (see page 658, Figure 4, ghrelin sequence is boxed).

Thus the claimed invention would have been obvious to the person of ordinary skill in the art at the time the invention was made.

Rejection of Claims 4, 6-8, 11-14, 31, 63, 68-70, 72, 73, 75, and 85 under 35 U.S.C. 103(a) as being unpatentable over Sebbel et al., (US Patent 6,964,769 B2, herein, "Sebbel") in view of Kojima et al (Nature, 1999, herein, "Kojima") as applied to claims 1-3, 19, 21-30, 32-34, 55, 63, 64, and 77-84 above, and further in view of Vasiljeva et al. (FEBS Letters, 1998) and Maita et al. (Gen Pept Accession VCBPQB, 1971) **is maintained.**

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that the defects in Sebbel and Kojima cannot be remedied by Vasiljeva and Maita alone or in combination because Examiner has not demonstrated a motivation to combine Vasiljeva and Maita. Particularly Applicant argues that Vasiljeva reference does not disclose or suggest attaching a 5 amino acid short peptide to the Qß coat protein using a non-peptide bond. It is noted that the limitation of a "non-peptide bond" is taught by Sebbel as discussed in the rejection above. Vasilhjeva was cited for the purpose of showing that antigen conjugated bacteriophages (generally taught by Sebbel) such as a specific RNA Qß bacteriophage, have been known and used in the art at the time the present invention was made. Maita complements the teaching of Vasiljeva by disclosing the RNA Qß bacteriophage which sequence is identical to the currently claimed SEQ ID NO: 4. Thus it would have been obvious to provide Sebbel's composition

comprising Vasiljeva's and Maita's RNA Qß bacteriophage and Kojima's ghrelin peptide, because Vasiljeva teaches that the recombinant RNA Qß bacteriophage particles are effective for induction of desired immune responses to the coupled antigenic determinants.

Thus for the reasons discussed above the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Stacy B. Chen/ 7-19-2007
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